

08-25-05

1623

PTO/SB/21 (02-04)

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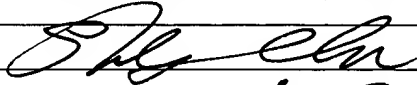
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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>		Application Number	09/976,468
		Filing Date	10/12/2001
		First Named Inventor	Gorge DiMartino
		Art Unit	1623
		Examiner Name	Lewis, Patrick T.
Total Number of Pages in This Submission	5	Attorney Docket Number	12636-219

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	Shirley Chen, Reg. No. 44,608, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	8-23-05

Express Mail Date: August 23, 2005**Express Mail Label No.: EV 518897145 US**

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EXPRESS MAIL LABEL NO.: EV 518897145 US

PATENT
Attorney Docket No. 12636-219

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Gorge DIMARTINO, et al.

Group Art Unit: 1623

Serial Number: 09/976,468

Examiner: LEWIS, Patrick T.

Filing Date: October 12, 2001

CONFIRMATION NO: 9964

Title: COMPOSITION AND METHOD FOR
TREATING GRAFT-VERSUS-HOST
DISEASE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

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☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;
-- OR --
- ☐ (3) It is being filed before the mailing date of the first Office Action on the merits;
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☒ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;
-- OR --
- ☒ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.
-- OR --
- ☐ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-219).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: _____

8-23-05

By: _____



Shirley Chen, Reg. No. 44,608

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971



PTO/SB/08B (07-05)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/976,468
				Filing Date	10/12/2001
				First Named Inventor	Jorge DiMartino
				Art Unit	1623
				Examiner Name	Lewis, Patrick T.
Sheet	1	of	1	Attorney Docket Number	12636-219

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ARAI, S. et al., "Management of graft-versus-host disease", <i>Blood Reviews</i> (2000) 14:190-204	
		DE LIMA, M., "GVHD Prophylaxis With Tacrolimus, Mini-methotrexate, and Pentostatin: A Phase I/II Study", Revitalization of Pentostatin: A New Approach To The Management of GVHD and Allogeneic Transplants. Satellite Symposium at the 2004 Tandem BMT meetings. February 15, 2004; Orlando, Florida.	
		DE LIMA, M. et al., "Pentostatin, Tacrolimus, and "Mini"-Methotrexate for Graft-Versus-Host Disease (GVHD) Prophylaxis: A Phase I/II Controlled, Randomized Study", <i>Blood</i> , (November 16, 2004), 104(11), abst 727.	
		FOSS, F. et al., "Reduced-Intensity Conditioning for Allogeneic Transplantation", Revitalization of Pentostatin: A New Approach To The Management of GVHD and Allogeneic Transplants. Satellite Symposium at the 2004 Tandem BMT meetings. February 15, 2004; Orlando, Florida.	
		HIGMAN, M. et al., "Pentostatin - Pharmacology, immunology, and clinical effects in graft-versus-host disease", <i>Expert Opinion</i> , (2004) 5(12): 2605-2613	
		JACOBSON, D. et al., "Novel Pharmacotherapeutic Approaches to Prevention and Treatment of GVHD", <i>Drugs</i> 2002; 62(6): 879-889	
		JACOBSON, D. et al., "Pentostatin: Efficacy in Refractory Chronic GVHD in Children", <i>Blood</i> , (November 16, 2004), 104(11), abst 2249.	
		SANDMAIER, B. et al., "Nonmyeloablative Hematopoietic Cell Transplantation for Patients With Hematologic Malignancies", Revitalization of Pentostatin: A New Approach To The Management of GVHD and Allogeneic Transplants. Satellite Symposium at the 2004 Tandem BMT meetings. February 15, 2004; Orlando, Florida.	

Examiner signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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